

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA)
v.)
JOHN BRUENS, MARY STEWART,)
MELISSA VAUGHN, and)
MARC SIROCKMAN)
Defendants.)
)

DEFENDANTS' PROPOSED JURY INSTRUCTIONS

Pursuant to Fed. R. Crim. P. 30, the Defendants hereby submit this First Set of Proposed Jury Instructions. Defendants expressly reserve the right to amend and supplement these instructions as necessary.

Respectfully submitted,

**JOHN BRUENS, MARY STEWART,
MELISSA VAUGHN, and MARC SIROCKMAN,**

By their undersigned attorneys.

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Dated: April 12, 2007

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 1**The Charge - The Indictment**

The defendants are charged by what is called an indictment. An indictment is merely a formal method used by the government to accuse a defendant of a crime. The indictment is not evidence of any kind. You may not consider the fact that the defendants were charged with a crime as evidence that any defendant committed a crime. Even though this indictment has been returned against these defendants, each defendant begins this trial with a “clean slate”—that is, with absolutely no evidence against him or her. The defendants are being tried together because the government has charged that they acted together in committing the crime of conspiracy. But you will have to give separate consideration to the case against each defendant and not think of the defendants as a group.

Each defendant has pled “Not Guilty” to this indictment and, therefore, denies the charges set forth in the indictment.¹

¹See 1A K. O’Malley, J. Grenig & W. Lee, *Federal Jury Practice and Instructions* §§ 13.04, 12.10 (5th ed. 2000); Pattern Jury Instructions of the First Circuit, Nos. 1.02, 3.08; *United States v. Garcia*, 562 F.2d 411, 417 (7th Cir. 1977) (“To the degree an uninstructed jury considers the matter, there is a real possibility that a charge leveled by a grand jury composed of its peers will weigh in the petit jury’s balance on the side of guilt.”).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 2

Defendants Charged Only With Acts in Indictment

You are here to decide whether the government has proved beyond a reasonable doubt that a defendant is guilty of the crime charged. The defendants are not on trial for any act, conduct, or offense not specifically charged in the indictment. Neither are you concerned with the guilt of any other person or persons not on trial as a defendant in this case.¹

¹Pattern Jury Instructions of the District Judges Ass'n of the Fifth Circuit, Criminal Cases, Instruction No. 1.19 (2001); 1A K. O'Malley, J. Grenig & W. Lee, *Federal Jury Practice and Instructions* §§ 12.09 (5th ed. 2000).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 3**Presumption of Innocence and Burden of Proof**

It is a cardinal principle of our system of justice that every person accused of a crime is presumed to be innocent unless and until his or her guilt is established beyond a reasonable doubt. The presumption is not a mere formality. It is a matter of the most important substance.

The presumption of innocence alone may be sufficient to raise a reasonable doubt and to require the acquittal of a defendant. The defendants before you each have the benefit of that presumption throughout the trial, and you are not to convict any defendant of any charge unless you are persuaded of a defendant's guilt of a particular charge beyond a reasonable doubt.

The presumption of innocence until proven guilty means that the burden of proof is always on the government to satisfy you that a defendant is guilty of the crime with which he or she is charged beyond a reasonable doubt. It is always the government's burden to prove each of the elements of the crimes charged against each defendant separately and independently beyond a reasonable doubt by the evidence and the reasonable inferences to be drawn from that evidence.

This burden of proof never shifts to any defendant. The law never imposes upon a defendant the burden or duty of calling any witnesses or producing any evidence. No defendant is even obligated to produce any evidence by cross-examining the witnesses for the government. Each defendant has the right to rely solely and completely upon the failure or inability of the government to establish beyond a reasonable doubt any essential element of a crime charged against him or her.¹

¹Pattern Jury Instructions of the First Circuit, No. 3.02; 1A K. O'Malley, J. Grenig & W. Lee, *Federal Jury Practice and Instructions* § 12.10 (5th ed. 2000).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 4**Reasonable Doubt**

Reasonable doubt is a strict and heavy burden. It does not mean that a defendant's guilt must be proved beyond all possible doubt, but it absolutely requires that the evidence exclude any reasonable doubt about a defendant's guilt.

A reasonable doubt may arise not only from the evidence produced but also from a lack of evidence. Reasonable doubt exists when, after weighing and considering all the evidence, using reason and common sense, jurors cannot say that they have a settled conviction of the truth of the charge.

Of course, a defendant is never to be convicted on suspicion or conjecture. If, for example, you view the evidence in the case as reasonably permitting either of two conclusions—one that a defendant is guilty as charged, the other that the defendant is not guilty—you must find the defendant not guilty.

It is not sufficient for the Government to establish a probability, even a strong one, that a fact charged is more likely to be true than not true. That is not enough to meet the burden of proof beyond reasonable doubt. On the other hand, there are very few things in this world that we know with absolute certainty, and in criminal cases the law does not require proof that overcomes every possible doubt.

What the Government must do to meet its heavy burden is to establish the truth of each part of each offense charged against each individual defendant by proof that convinces you and leaves you with no reasonable doubt, and thus satisfies you that you can, consistently with your solemn oath as jurors, base your verdict upon it. If you so find as to a particular charge against a particular defendant, you may return a verdict of guilty on that charge. If, on the other hand, you

think there is a reasonable doubt about whether a defendant is guilty of a particular offense, you must give the defendant the benefit of the doubt and find the defendant not guilty of that offense.¹

¹*United States v. Cleveland*, 106 F.3d 1056, 1062-63 (1st Cir. 1997), *aff'd sub nom. Muscarello v. United States*, 524 U.S. 125 (1998); *see also* Pattern Jury Instructions of the First Circuit, No. 3.02, comment 4.

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 5**What is Evidence**

The evidence in this cases consists of: (1) the sworn testimony of witnesses, both on direct and cross-examination, regardless of who called the witness; (2) the exhibits that have been received into evidence; and (3) any facts to which the lawyers have agreed or stipulated. If a piece of evidence has been limited to any one defendant, you may only consider that piece of evidence when considering the innocence or guilt of that defendant; it may not form any basis for your conclusion with respect to any other defendant.

A stipulation means simply that the government and the defendants accept the truth of a particular proposition or fact. Since there is no disagreement, there is no need for evidence apart from the stipulation. You may accept the stipulation as fact to be given whatever weight you choose.

Documentary evidence is no more or less important or reliable than the testimony of witnesses. A document is just a human being expressing a view. You have to look very carefully. You have to consider the circumstances of the creation of that document to understand the import of that document. With the development of voicemails and e-mails, people are much more informal in the way they speak. You have to evaluate documentation in the context of what does it really mean, understanding that people, because they're trying to run things off quickly, misspell, mischaracterize, awkwardly characterize. What does that mean? It means that you are going to look at those documents with a careful discrimination that you apply and will apply to the testimony of witnesses.

Although you may consider only the evidence presented in the case, you are not limited in considering that evidence to the bald statements made by the witnesses or contained in the

documents. In other words, you are not limited solely to what you see and hear as the witnesses testify. You are permitted to draw from facts that you find to have been proven such reasonable inferences as you believe are justified in the light of common sense and personal experience.¹

¹Pattern Jury Instructions of the First Circuit, No. 3.04; *see also* 1A K. O'Malley, J. Grenig & W. Lee, *Federal Jury Practice and Instructions* § 12.03 (5th ed. 2000).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 6

Credibility of Witnesses

In deciding what the facts are, you may have to decide what testimony you believe and what testimony you do not believe. You may believe everything a witness says, part of it, or none of it.

In deciding what to believe, you may consider a number of factors, including: (1) the witness's ability to see or hear or know the things the witness testifies to; (2) the quality of the witness's memory; (3) the reasonableness or unreasonableness of the recollections they provide you; (4) the witness's manner while testifying; (5) whether the witness has an interest in the outcome of the case or any motive, bias or prejudice; (6) whether the witness is contradicted by anything he or she said or wrote before trial or by other evidence; (7) whether the testimony is consistent or inconsistent with other witnesses' testimony; and (8) how reasonable the witness's testimony is when considered in the light of other evidence which you believe.¹

¹Pattern Jury Instructions of the First Circuit, No. 1.06.

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 7

Caution as to Testimony of Whistleblowers

You have heard the testimony of Kim Jackson and William Frye who received money from the government as a result of settlements they entered into in a separate civil case.

That receipt of money constitutes a benefit Ms. Jackson and Mr. Frye received from the government. You may consider that fact in weighing the credibility of the testimony of Ms. Jackson and Mr. Frye. The fact that someone received a benefit from one of the parties might mean that person has a predisposition for one of the parties. You may consider whether or not the testimony you heard was in some fashion influenced by the receipt of a relatively large amount of money. Some people in such a situation you might find have a tendency perhaps to tailor the truth; others may not. You must consider the testimony of Ms. Jackson and Mr. Frye with care and receive it with caution to make a determination whether or not he/she is in some fashion influenced in a way that would influence how you evaluate his/her credibility.¹

¹ Pattern Jury Instructions of the First Circuit, No. 2.07.

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 8

Evidence of Corporate Settlement Received for Limited Purpose

You must consider evidence regarding Serono's civil settlement with the government only for the purpose of evaluating the credibility of the beneficiaries of that settlement, which include, as I said, Ms. Jackson and Mr. Frye. You must not consider the fact that Serono settled a separate, civil action for purposes of determining whether or not any of the individual defendants here are guilty of wrongdoing.

As I told you at the outset, your verdict as to each defendant must be considered separately based on the evidence in this case. Serono's resolution of a different case, which is something that may factor into your consideration of the credibility of Ms. Jackson and Mr. Frye, must not be considered in any way as an indication that any of these defendants are guilty or that there is any evidence that these defendants are guilty.

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 9**Caution as to Testimony of Witness Who Pled Guilty**

You heard the testimony of Adam Stupak, who testified pursuant to a plea agreement in this case. As I have repeatedly instructed you, you must consider the evidence against each defendant separately. You must not consider Adam Stupak's guilty plea as evidence of the guilt of any of the defendants. That Mr. Stupak pled guilty to an offense does not mean that any individual defendant before you is guilty or even that it is more likely that any individual defendant before you is guilty. Rather, you may consider the fact that Mr. Stupak's pled guilty only for the purpose of determining how much, if at all, to rely on his testimony.

The testimony of a person who testifies pursuant to a plea agreement must be weighed with caution and greater care than the testimony of a witness who has not pled guilty to a crime. You must consider whether the testimony of Mr. Stupak was affected by self-interest, by his agreement with the government, by his interest in the outcome of this case, or by prejudice against any defendant. For example, a witness who realized that he may obtain a more favorable outcome for his own case by incriminating another has a motive to give false testimony. You must consider such factors and give the witness' testimony the weight you feel it deserves.¹

¹See 1A K. O'Malley, J. Grenig & W. Lee, *Federal Jury Practice and Instructions* § 15.04 (5th ed. 2000); Pattern Jury Instructions of the First Circuit, No. 2.07.

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 10

What is Not Evidence

Certain things are not evidence. I will list them for you:

(1) Arguments and statements by lawyers are not evidence. The lawyers are not witnesses.

What they say in their opening statements, closing arguments and at other times is intended to help you interpret the evidence, but it is not evidence. If the facts as you remember them from the evidence differ from the way the lawyers have stated them, your memory of them controls.

(2) Questions and objections by lawyers are not evidence. Lawyers have a duty to their clients to object when they believe a question is improper under the rules of evidence. You should not be influenced by the objection or by my ruling on it.

(3) Anything that I have excluded from evidence or ordered stricken and instructed you to disregard is not evidence. You must not consider such items.

(4) Anything you may have seen or heard outside the courtroom is not evidence and must be disregarded. This includes any press, radio, or television reports you may have seen or heard. You are to decide the case solely on the evidence received at trial.

(5) The indictment is not evidence. This case, like most criminal cases, began with an indictment. That indictment was returned by a grand jury, which heard only the government's side of the case. I caution you, as I have before, that the fact that defendants had an indictment filed against them is no evidence whatsoever of any defendant's guilt. The indictment is simply an accusation. It is the means by which the allegations and charges of the government are brought before this court. The indictment adds nothing to the Government's case against any of

the defendants.¹

¹Pattern Jury Instructions of the First Circuit, No. 3.08.

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 11

Give Each Defendant Separate Consideration

It is your duty to give separate and personal consideration to the case of each defendant.

When you do so, you should analyze what the evidence in the case shows with respect to that defendant leaving out of consideration entirely any evidence admitted solely against some other defendant or defendants.

Each defendant is entitled to have his or her case determined from evidence as to his or her own acts, statements, and conduct and any other evidence in the case which may be applicable to him or her.

The fact that you return a verdict of guilty or not guilty to one defendant should not, in any way, affect your verdict regarding any other defendant.

Unless specifically directed otherwise, the jury must consider each instruction given by the Court to apply separately and individually to each defendant on trial in this case.¹

¹1A K. O'Malley, J. Grenig & W. Lee, *Federal Jury Practice and Instructions* §§ 12.14, 12.15 (5th ed. 2000).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 12**Defendants' Right Not to Testify or Present a Defense**

Each defendant has an absolute right under our Constitution not to testify. The fact that a defendant did not testify must not be discussed or considered in any way in arriving at your verdict. No inference of any kind may be drawn from the fact that a defendant decided to exercise his or her privilege under the Constitution not to testify. For any of you to draw such an inference would be wrong; indeed, it would be a violation of your oath as a juror.

Remember, as I previously stated, the law never imposes upon a defendant the burden or duty of calling any witnesses or of producing any evidence. The burden always rests with the Government and you should understand that the defendants are sometimes at a disadvantage if they do seek to call a reluctant witness because only the Government has the power to enter into immunity agreements or request an order of immunity from the Court. And you've seen witnesses in this case who declined to testify unless they had a grant of immunity. The burden of proving the charge beyond reasonable doubt always rests with the government, and it never shifts to a defendant, even if a defendant decides to present some evidence on his or her own behalf.¹

¹See 1A K. O'Malley, J. Grenig & W. Lee, *Federal Jury Practice and Instructions* § 15.14 (5th ed. 2000); Pattern Jury Instructions of the First Circuit, No. 3.03.

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 13

Not Here to Make Policy

This isn't a referendum about health care policy in the United States. It may be that you are in favor of more patient choice in the selection of prescription medicines. It may be that you believe that prescription medications are too expensive. It may be that you find the incentive structure that surrounds the delivery of medical care, medical equipment, medical services, or prescription medicines to be previous or wrong. But that's not what this case is about. That's only the environment we're talking about. What we're talking about here is whether a particular criminal violation has been proved in this environment.¹

¹ *United States v. MacKenzie, et al.*, CR-01-10350 (D.Mass. 2004) (instruction given to jury).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 14

No Criminal Responsibility Solely Based on Position in Company

A defendant is not criminally responsible for any unlawful acts of any other employee of a corporation merely because the defendant held an executive, managerial, or supervisory position within the corporation. Each defendant is criminally responsible only if you find beyond a reasonable doubt that the government has proven each and every element of each offense charged against a particular defendant.¹

¹See 1A K. O'Malley, J. Grenig & W. Lee, *Federal Jury Practice and Instructions* § 18.04 (5th ed. 2000).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 15

Impermissible To Infer Participation From Mere Presence

You may not infer that a defendant is guilty of participating in criminal conduct merely from the fact that he or she was present in the vicinity at the time criminal conduct was being committed.

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 16

Count 1 of the indictment alleges that, from March 1, 1999 through December 1999, each of the defendants engaged in a conspiracy to violate the Anti-Kickback Statute by:

Knowingly and willfully offer[ing] and giv[ing] remuneration, in cash and in kind, including kickbacks, bribes and rebates, directly and indirectly, and overtly and covertly, to physicians and other customers for purchasing and ordering and for recommending to patients and others that they purchase and order the drug Serostim, for which drug payment was made in whole and in part by the Medicare and Medicaid and other federal health care programs.¹

¹ See 42 U.S.C. § 1320a-7b(b)(1) and (b)(2).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 17

Conspiracy Elements

You must consider the charge and evidence against each defendant separately. For you to find any defendant guilty of the conspiracy alleged in this indictment, the government must prove each of the following elements as to that defendant:

First, the government must prove beyond a reasonable doubt that the agreement specified in the indictment, and not some other agreement or agreements, existed between at least two people to violate the Anti-Kickback Statute;

Second, the government must prove beyond a reasonable doubt that, for each defendant considered separately, the defendant willfully joined in that agreement with the specific intent to further the conspiracy's unlawful objectives of violating the Anti-Kickback Statute and did so with the intent necessary to violate that statute; and

Third, the government must prove beyond a reasonable doubt that, during the existence of the conspiracy, one of the conspirators performed at least one overt act in furtherance of the conspiracy's unlawful objective.

These elements have a number of subparts to them, all of which must be proven by the government beyond a reasonable doubt. I will now describe each of these elements in detail:

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 18**1st Element: Agreement**

The first element which the government must prove beyond a reasonable doubt to establish the offense of conspiracy against any defendant is an agreement between two or more people to violate the Anti-Kickback Statute.

The government does not have to prove that this agreement was in writing or constituted a formal plan in which everyone involved sat down together and worked out all the details. But the government must prove beyond a reasonable doubt, for each defendant, that the defendant and at least one other person shared a general understanding about the crime they agreed to commit. The fact that a defendant and various other people engaged in similar conduct, or associated with each other, or discussed common aims and interests—or even the fact that a defendant may have known criminal conduct was taking place at his or her company—are all facts which by themselves do not establish the existence of an agreement. Whether an agreement to violate the law existed between a defendant and another person is for you to decide after weighing all the evidence.¹

¹See Pattern Jury Instructions of the First Circuit, No. 4.03; 2 K. O'Malley, J. Grenig & W. Lee, *Federal Jury Practice and Instructions* § 31.05 (5th ed. 2000).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 19

Agreement Cannot Be With Corporation

In addition, the government must prove beyond a reasonable doubt that the agreement to violate the law was with another person, not with a corporation. If you find that a defendant acted alone on behalf of Serono, and not as part of an agreement with other people, that defendant cannot be convicted of conspiracy.¹

¹*United States v. Peters*, 732 F.2d 1004, 1008 n.6 (1st Cir. 1984) (“a corporate officer, acting alone on behalf of the corporation, could not be convicted of conspiring with the corporation”); *United States v. Becuvalas*, 909 F.2d 593, 496 n.7 (1st Cir. 1990) (corporation and its president “cannot legally conspire with each other”).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 20

2d Element: Intent

If you conclude from the evidence beyond a reasonable doubt that the conspiracy charged in the indictment did exist, then you must determine whether the government has proved the second essential element of the crime of conspiracy beyond a reasonable doubt. That is, you must determine, as to each defendant, whether the defendant acted knowingly, willfully, and with the specific intent both to join in the conspiracy and to further the conspiracy's alleged unlawful objectives of violating the Anti-Kickback Statute.

I will now instruct you further as to the meaning of the terms "knowingly," "willfully," and "specific intent."

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 21**Knowingly**

To prove that a defendant "knowingly" entered into an illegal conspiracy, the government must prove beyond a reasonable doubt, as to each defendant, that the defendant had knowledge of the facts which made his or her conduct illegal; that is, that the defendant acted voluntarily and intentionally and not because of mistake or accident.¹

It is not sufficient for the government to prove that a defendant should have had knowledge of particular facts merely because of the position he or she had at Serono. The government must prove beyond a reasonable doubt, as to each defendant, that the defendant had actual knowledge of the facts that made his or her conduct unlawful.²

¹See Pattern Jury Instructions of the First Circuit, No. 2.14, Comment, and cases cited therein; *Staples v. United States*, 511 U.S. 600, 614-15 (1994) ("knowing" requires proof petitioner knew of the features of his firearm which brought it within scope of prohibition).

²See *United States v. MacDonald & Watson Waste Oil Co.*, 933 F.2d 35, 55 (1st Cir. 1991) ("In a crime having knowledge as an express element, a mere showing of official responsibility . . . is not an adequate substitute for direct or circumstantial proof of knowledge.").

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 22**Willfully**

To prove that a defendant “willfully” entered into an illegal conspiracy, the government must prove beyond a reasonable doubt, as to each defendant, that the defendant acted voluntarily and intelligently and with the specific intent that the underlying crime be committed—that is to say, with bad purpose, either to disobey or disregard the law—and not to act by ignorance, accident or mistake. If you do not find beyond a reasonable doubt that the defendant voluntarily and purposefully intended to disobey or disregard the law, you must find that defendant not guilty.¹

¹See Pattern Jury Instructions of the First Circuit, No. 4.03; *United States v. Monteiro*, 871 F.2d 204, 208-09 (1st Cir. 1989).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 23**Specific Intent to Participate in Conspiracy**

I have used the term “specific intent.” The government must prove beyond a reasonable doubt two types of intent: a specific intent to participate in the conspiracy and a specific intent that the underlying crimes be committed.¹

Proof that a defendant specifically intended to participate in the conspiracy must be based only on that defendant’s own words or actions, not mere association or even knowledge of wrongdoing.² The fact that a defendant worked at a company where a conspiracy may have been carried out or associated with colleagues who may have been conspirators does not establish a defendant’s specific intent to participate in that conspiracy. A person cannot be found to have entered into an agreement with other employees of a corporation based solely on their title or functions within the corporation.³

You need not find that a defendant agreed specifically to or knew about all the details of the crime, or knew every co-conspirator, or participated in each act, or played a major role. But, the government must prove beyond a reasonable doubt, for each defendant, that the defendant knew the essential features and general aims of the conspiracy and specifically intended to join

¹See Pattern Jury Instructions of the First Circuit, No. 4.03. See also *United States v. Cintolo*, 818 F.2d 980, 1003-04 (1st Cir. 1987) (court’s instruction requiring proof that defendant had specific intent to join conspiracy was correct statement of law), *cert. denied*, 484 U.S. 913 (1987); *United States v. Brandon*, 17 F.3d 409, 428 (1st Cir. 1994), *cert. denied sub nom.*, *Granoff v. United States*, 513 U.S. 820 (1994).

²*United States v. Richardson*, 225 F.3d 46, 53-54 (1st Cir. 2000) (defendant’s guilt “could only be established by his own words or actions”), *cert. denied*, 121 S. Ct. 1216 (2001); *United States v. Rengifo*, 858 F.2d 800, 808 (1st Cir. 1988), *cert. denied*, 490 U.S. 1023 (1989); Pattern Jury Instructions of the First Circuit, No. 4.03.

³See, e.g., *United States v. Hyson*, 721 F.2d 856, 862 (1st Cir. 1983); *Richardson*, 225 F.3d at 53-54.

it. Even if the defendant was not part of the agreement at the very start, he or she can be found guilty of conspiracy if the government proves beyond a reasonable doubt that the defendant willfully joined the conspiracy after it formed. On the other hand, a person who has no knowledge of a conspiracy, but simply happens to act in a way that furthers some object or purpose of the conspiracy, does not thereby become a conspirator.⁴

⁴Pattern Jury Instructions of the First Circuit, No. 4.03.

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 24

Specific Intent to Violate the Law

The second type of intent which the government must prove beyond a reasonable doubt before a defendant can be found to have knowingly and willfully joined the alleged conspiracy is the specific intent to violate the law.¹ Count 1 of the indictment alleges that the defendants specifically intended to violate the Anti-Kickback Statute.

¹Pattern Jury Instructions of the First Circuit, No. 4.03; *see also United States v. Cintolo*, 818 F.2d 980, 1003-04 (1st Cir. 1987) (court's instruction requiring proof that defendant had specific intent to commit substantive offense was correct statement of law), *cert. denied*, 484 U.S. 913 (1987); *United States v. Brandon*, 17 F.3d 409, 428 (1st Cir. 1994), *cert. denied sub nom.*, *Granoff v. United States*, 513 U.S. 820 (1994).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 25**Second Object: Anti-Kickback Statute**

The law that defendants allegedly conspired to violate is the Anti-Kickback Statute:

Knowingly and willfully offer[ing] and giv[ing] remuneration, in cash and in kind, including kickbacks, bribes and rebates, directly and indirectly, and overtly and covertly, to physicians and other customers for purchasing and ordering and for recommending to patients and others that they purchase and order the drug Serostim, for which drug payment was made in whole and in part by the Medicare and Medicaid and other federal health care programs.

In this case, to prove that a defendant specifically intended to violate the Anti-Kickback Statute, the government must prove four elements beyond a reasonable doubt:

First, that the defendant offered or paid remuneration to any physician or other customer of Serono;

Second, that the remuneration was offered or paid to induce the customer to purchase or order, or recommend to others that they purchase or order, the drug Serostim;

Third, that payment for Serostim that was purchased as a result of the inducement, would be made in whole or in part by the Medicare or Medicaid program;

Fourth, that the defendant acted knowingly and willfully, as I will define those terms for you in a moment, when that defendant offered or paid the remuneration to induce such purchases or orders.¹

I will now explain each of the elements of the Anti-Kickback Statute in more detail.

¹42 U.S.C. § 1320a-7b(b)(1) and (b)(2).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 26

Remuneration Defined

Remuneration means anything of substantial independent value to the recipient, regardless of whether it is provided directly or indirectly, overtly or covertly, in cash or in kind. The Anti-Kickback Statute does not prohibit all remuneration. A remuneration is illegal under the Anti-Kickback Statute only when all of the other elements of the Anti-Kickback Statute are met.¹

¹See 42 U.S.C. § 1320a-7b(b)(2); *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731, 23735 (May 5, 2003).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 27**Inducement**

It is not improper, in itself, for a seller of pharmaceuticals to offer or pay something of value to a physician. Providing remuneration to a physician will violate the Anti-Kickback Statute only if the remuneration was offered or paid with the specific criminal intent to induce the purchase of a drug that may be paid for by a federal health care program.

“To induce” a purchase means to offer or pay remuneration for the explicit purpose of causing a physician to purchase certain drugs in return for the payment of the remuneration.

It is not a basis for conviction under the Anti-Kickback Statute that a person merely hoped or expected or believed that purchases would ensue from the payment of remuneration to a physician that was designed for other purposes. Likewise, simply providing a physician an opportunity to attend a medical conference does not constitute inducement. Rather, the statutory requirement of improper inducement is satisfied only if the remuneration is offered or paid with the intent that the physician will recommend to patients that they purchase or order additional drugs in exchange for the payment of the remuneration.¹

¹See 42 U.S.C. § 1320a-7b(b)(1)-(2); *United States v. MacKenzie, et al.*, CR-01-10350 (D.Mass. 2004) (instruction given to jury). See also *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 29-30 (1st Cir. 1989) (approving jury instruction requiring that government prove payments in Anti-Kickback Statute were made with “a corrupt intent” or an “improper purpose”).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 28**Dual Purposes**

The intent to induce must be the primary reason the remuneration was offered or paid. If you find beyond a reasonable doubt that the sole or exclusive purpose of the remuneration was to induce the purchase of drugs, you may find that the remuneration violated the Anti-Kickback Statute, provided all the other elements of the offense have been met. However, if you find that remuneration was offered or paid for more than one purpose, then the government must prove beyond a reasonable doubt that the primary purpose of the remuneration was to induce the purchase of drugs payable by Medicare or Medicaid. If you do not find beyond a reasonable doubt that the primary purpose of the remuneration was to induce the purchase of Serostim, you cannot find defendants guilty of conspiring to violate the Anti-Kickback Statute.¹

¹See *Bay State Ambulance*, 874 F.2d. at 33 (approving instruction that “[i]f you find that payments were made for two or more purposes, then the Government has to prove that the improper purpose is the primary purpose or was the primary purpose in making and receiving payments” and noting “The key to a Medicare Fraud case is the reason for the payment—was the purpose of the payments primarily for inducement.”).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 29

Cultivating A Business Relationship Not Improper

A person does not violate the Anti-Kickback Statute by providing remuneration or other benefits solely as part of the routine cultivation of a business relationship, rather than with the intent to induce specific purchases. If you find that as to any particular transaction there was both the intent to cultivate a business relationship, and an intent to induce purchases, then you must consider whether the intent to induce was the primary purpose of any alleged conspiracy relating to that transaction.¹

¹ *United States v. MacKenzie, et al.*, CR-01-10350 (D.Mass. 2004) (instruction given to jury)

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 30**Knowing and Willful Conduct**

A person may violate the Anti-Kickback Statute only by acting knowingly and willfully.

Therefore, to prove that a defendant specifically intended to violate the Anti-Kickback Statute, the government must prove beyond a reasonable doubt that the defendant was aware of the existence of the Anti-Kickback Statute, knew of the conduct that it prohibited, and despite that awareness and knowledge engaged in conduct with the specific intent to disobey that law.¹

¹See *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995) (applying *Ratzlaf v. United States* to phrase “knowingly and willfully” in Anti-Kickback Statute to require that defendant “(1) know that [the Act] prohibits offering or paying remuneration to induce” Medicare business “and (2) engage in prohibited conduct with the specific intent to disobey the law”); *United States v. Bay State Ambulance and Hospital Rental Service, Inc.*, 874 F.2d 20, 33 (1st Cir. 1989) (noting that Medicare fraud includes “a second and stronger scienter requirement” in addition to knowing and willful conduct); *see also Ratzlaf v. United States*, 510 U.S. 135, 141-43 (1994) (holding that willfulness as element of anti-structuring provision of Money Laundering Control Act requires proof of both knowledge of reporting requirement and specific intent to commit crime of structuring).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 31**Good Faith Defense**

A defendants' good faith belief that his or her conduct was lawful is an absolute defense to the charge of conspiring to violate, or violating, the Anti-Kickback Statute because good faith is inconsistent with willfulness. If a defendant acted based on a belief or opinion that he or she honestly held, the defendant's actions are not criminal merely because his or her belief or opinion turned out to be inaccurate, incorrect or wrong. A person's honest mistake in judgment does not rise to the level of criminal conduct and cannot be punishable under the Anti-Kickback Statute merely because the belief or opinion turns out to be inaccurate, incorrect or wrong.

While good faith has no precise definition, it encompasses, among other things, a belief or opinion honestly held, an absence of malice or ill will, and an intention to avoid taking unfair advantage of another. In determining whether the government has proven the defendant's willfulness beyond a reasonable doubt or whether there is a reasonable doubt such that the defendant instead may have acted in good faith, you must consider all of the evidence that bears on his or her state of mind.

The burden of proving good faith does not rest with the defendants because a defendant has no obligation to prove anything in this case. It is the government's burden to prove to you, beyond a reasonable doubt, that a defendant acted willfully. If the evidence leaves you with a reasonable doubt whether the defendant acted willfully with the intent to violate the law or in good faith, you must find him or her not guilty.¹

¹See 1A K. O'Malley, J. Grenig & W. Lee, Federal Jury Practice and Instructions, § 19.06 (5th ed. 2000) (modified).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 32**3d Element: Overt Act**

If you unanimously agree, as to a particular defendant considered separately, that the defendant and at least one other person entered into the agreement alleged in the indictment, and that the defendant did so knowingly and willfully and with the specific intent both to join the conspiracy and the specific intent to further its unlawful objective, you must then address the third necessary element of the conspiracy charge, the overt act.

The government must prove beyond a reasonable doubt that one of the conspirators knowingly and willfully performed at least one overt act in the District of Massachusetts during the existence of the conspiracy. An overt act is any act knowingly and willfully committed by one or more of the conspirators in an effort to accomplish some purpose of the conspiracy.

In order for you to find that an overt act was performed, each of you must unanimously agree that the government has proven the same overt act beyond a reasonable doubt. Only one overt act has to be proven. The overt act must have been committed in the District of Massachusetts.¹

¹See Pattern Jury Instructions of the First Circuit, No. 4.03; 2 K. O'Malley, J. Grenig & W. Lee, Federal Jury Practice and Instructions, § 31.07 (5th ed. 2000). *Grunewald v. United States*, 353 U.S. 391, 397 (1957); *United States v. Falcone*, 311 U.S. 205, 210 (1940); *United States v. Flaherty*, 668 F.2d 566, 580 n.4 (1st Cir. 1981); *United States v. North*, 900 F.2d 131, 134 (8th Cir. 1990).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 33**Theory of Defense**

The defendants contend that their conduct was lawful. The defendants deny that they engaged in any conduct with an intent to disobey any laws.

The defendants also contend that at all times they acted pursuant to a good faith belief that their conduct was lawful and in compliance with all applicable laws or regulations. Keep in mind that the government has the burden of proving beyond a reasonable doubt that each defendant knowingly and willfully joined the conspiracy described in the indictment. If a defendant acted with a good faith belief that his or her conduct was in compliance with applicable laws and regulations, then that defendant cannot be said to have acted willfully, even if that belief was mistaken, and you must find that defendant not guilty as to the conspiracy count.¹

¹ See 1A K. O'Malley, J. Grenig & W. Lee, Federal Jury Practice and Instructions, § 19.06 (5th ed. 2000) (modified). See also *Ratzlaf v. United States*, 510 U.S. 135, 151-53 (1994); *Cheek v. United States*, 498 U.S. 192, 199-203 (1991); *United States v. Obiechie*, 38 F.3d 309, 315 (7th Cir. 1994); *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995).

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 34

Foreperson's Role; Unanimity

I come now to the last part of the instructions, the rules for your deliberations.

When you retire you will discuss the case with the other jurors to reach agreement if you can do so. You shall permit your foreperson to preside over your deliberations, and your foreperson will speak for you here in court. Your verdict must be unanimous.¹

¹Pattern Jury Instructions of the First Circuit, No. 6.01

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 35

Reaching Agreement

Each of you must decide the case for yourself, but you should do so only after considering all the evidence, discussing it fully with the other jurors, and listening to the views of the other jurors.

Do not be afraid to change your opinion if you think you are wrong. But do not come to a decision simply because other jurors think it is right.

This case has taken time and effort to prepare and try. There is no reason to think it could be better tried or that another jury is better qualified to decide it. It is important therefore that you reach a verdict if you can do so conscientiously. If it looks at some point as if you may have difficulty in reaching a unanimous verdict, and if the greater number of you are agreed on a verdict, the jurors in both the majority and the minority should reexamine their positions to see whether they have given careful consideration and sufficient weight to the evidence that has favorably impressed the jurors who disagree with them. You should not hesitate to reconsider your views from time to time and to change them if you are persuaded that this is appropriate.

It is important that you attempt to return a verdict, but, of course, only if each of you can do so after having made your own conscientious determination. Do not surrender an honest conviction as to the weight and effect of the evidence simply to reach a verdict.¹

¹Pattern Jury Instructions of the First Circuit, No. 6.03

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 36**Communication with the Court**

If it becomes necessary during your deliberations to communicate with me, you may send a note through the jury officer signed by your foreperson or by one or more members of the jury. No member of the jury should ever attempt to communicate with me on anything concerning the case except by a signed writing, and I will communicate with any member of the jury on anything concerning the case only in writing, or orally here in open court. If you send out a question, I will consult with the parties as promptly as possible before answering it, which may take some time. You may continue with your deliberations while waiting for the answer to any question. Remember that you are not to tell anyone—including me—how the jury stands, numerically or otherwise, until after you have reached a unanimous verdict or have been discharged.